

elf atochem

Contains No CBI

ELF ATOCHEM NORTH AMERICA, INC.
900 First Avenue, P.O. Box 1536
King of Prussia, PA 19406-0018

Tel: 215-337-6500

September 9, 1992

(A)

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

86HQ-92-12692

88920010571

ELF ATOCHEM

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e)
Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed study to establish eye irritation potential in rabbits for tributyltin oxide to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of Atochem.

The enclosed study provides information on the chemical tributyltin oxide. Its exact chemical name is hexabutyldistannoxane and its CAS number is 56-35-9.

The title of the enclosed study is Eye Irritation Range-Find: Tributyltin Oxide. The following is a summary of the adverse effects observed in this study.

Application of one-tenth (0.1) ml of tributyltin oxide into the right eye of one New Zealand white rabbit resulted in severe irritation with corneal damage.

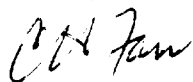
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2/9/95

TSCA CAP
Tributyltin Oxide
September 9, 1992
Page Two

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

A handwritten signature in cursive script, appearing to read "C.H. Farr".

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

✓ FILED: 1N00981-85

TR91-248
COPY 1 TBT

THE HINE LABORATORIES
RESEARCH AND DEVELOPMENT
1099 FOLSOM STREET • SAN FRANCISCO 3, CALIFORNIA

30 December 1964 T-132

Report No. 15
✓ Eye Irritation Range-find:
✓ Tributyltin Oxide
Lab. No. 81-32g

M & T Chemicals, Inc.
Rahway, New Jersey

Attention: Dr. C. Kenneth Banks

Gentlemen:

In accordance with your letter of 23 October, we have conducted an eye irritation range-find test on your product tributyltin oxide.

The methods used were as follows: 0.1 ml of tributyltin oxide was instilled in the right eye of one New Zealand white rabbit. The eye was held shut for 10 seconds and the animal returned to its cage. Readings were taken according to the method of Draize at 24, 48 and 72 hours after the exposure.

The following results were obtained: At 24 hours there was much swelling, discharge, and erythema. The lids could not be forced apart at this time to view the cornea and iris. The score assigned at 24 hours was 16. At 48 hours, although the swelling and redness remained the same, there was slightly less discharge and the lids could be opened. The cornea was almost completely opaque over its entire surface. The score assigned at this time was 98. At 72 hours the conditions were the same and the score of 98 was also given at this time. Seven days later the animal was sacrificed. At this time the cornea was still opaque and had been invaded by small blood vessels. This represents a severe reaction with corneal damage.

Supporting data will be found in the table on the following page.

Very truly yours,

C. H. Hine

C. H. Hine, M.D., Ph. D.
Director
The Hine Laboratories, Inc.

CAS 56-35-9

Table 1: Results of Eye Irritation Range-find Studies on Tributyltin Oxide

Rabbit No.	Time of Reading	Cornea		Iris	Conjunctiva		
		Opacity	Area		Redness	Discharge	Chemosis
A 54	24	?	?	?	2	3	4
A 54	48	4	4	?	2	3	4
A 54	72	4	4	?	2	3	4
<p style="text-align: right;">Scores: 24 hrs. - 16 48 hrs. - 98 72 hrs. - 98</p>							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C. H. Farr, PhD, DABT
Manager, Product Safety and Toxicology
Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12692A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: MAY 10 1995

NON-CAP

CAP

Submission number: 12692A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document

0

1

2

pages

1, 2

pages

1, 2, 3

Notes:

Contractor reviewer :

FOR

Date:

2/22/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: 1092-12692 SEQ. A

Submission # 8EHQ

TYPE: INT SUPP FLWP

SUBMITTER NAME: Elf Atochem North

America, Inc.

SUB. DATE: 09/09/92 OTS DATE: 10/06/92 CSRAD DATE: 02/09/95

CHEMICAL NAME: TBTO CAS# 56-35-9

- OPTIONAL ACTIONS:
- 0401 NO ACTION REPORTED
 - 0402 STUDIES PLANNED IN FUTURE
 - 0403 NOTIFICATION OF WORKING CONDITIONS
 - 0404 LABEL/MSDS CHANGES
 - 0405 PROCESS/HANDLING CHANGES
 - 0406 APP/USE DISCONTINUED
 - 0407 PRODUCTION DISCONTINUED
 - 0408 CONFIDENTIAL

INFORMATION REQUESTED: FLWP DATE:

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TECH)
- 0503 INFO REQUESTED (VOL ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

- 0639 REFER TO CHEMICAL SCREENING
- 0678 CAP NOTICE

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/RELEASE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

USE: PRODUCTION:

TOXICOLOGICAL CONCERN:

SPECIES

RBT

LOW

MED

HIGH

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

TRIAGE DATA: NON-CBI INVENTORY

YES

NO

IN TERMINI

CAS SR

109212

-CPSS- 0927952122

0 0 0 0 0 0 0 0 0 0 0
> <ID NUMBER>
8(e)-12692A

> <TOX CONCERN>
H

> <COMMENT>
EYE IRRITATION IN RABBITS IS HIGH CONCERN. 0.1 ML OF TEST MATERIAL WAS APPLIED TO THE EYE OF
1 ANIMAL AND RESULTED IN SEVERE IRRITATION WITH CORNEAL DAMAGE. CLINICAL OBSERVATIONS
INCLUDED SWELLING, DISCHARGE, AND ERYTHEMA. THE LIDS COULD NOT BE OPENED AT 24 HOURS IN
ORDER TO EVALUATE THE CORNEA OR IRIS. AT 48 HOURS THE LIDS WERE OPENED AND THE CORNEA
WAS COMPLETELY OPAQUE. THE IRRITATION SCORE WAS 98.

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